

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	:	
STANGEL, Peter	:	Group Art Unit: 3626
Serial No.: 09/772,394	:	Examiner: BUI, Kim T.
Filed: March 30, 2001	:	
For: Clinical Care Utilization Management System	:	

RESPONSE UNDER 37 C.F.R. §1.116

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Commissioner for Patents
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SIR:

In response to the Office Action dated January 20, 2006, please amend the above-identified application as follows:

Amendments to the Specification begin on page 2 of this paper

Amendments to the Claims are reflected in the listing of claims which begins on page 3 of this paper.

Remarks/Arguments begin on page 11 of this paper.

AMENDMENTS TO THE SPECIFICATION

Please amend the Abstract as follows:

A computer implemented system facilitates the submission of clinical events ~~date~~ data to a reviewing agency by prompting for ~~date~~ data needed to authorize the appropriateness of the event. The system directs an appropriate submission to authorize the event. The system further stores the patient clinical event data and presents the ~~date~~ data for review. The system confirms that the clinical event is appropriate by referring to the input data and predetermined validation rules.

AMENDMENTS TO THE CLAIMS

Please amend the claims as follows:

1. (Currently Amended) A computer implemented system, ~~consisting of one or more computers connected by one of an internet and a local area network for generating an electronic clinical record of a patient clinical encounter for submission for review by a health care reviewing organization, comprising:~~

at least one user selection interface module, wherein the at least one user interface module facilitates generation of an electronic record of a patient clinical encounter by presenting a user interface comprising a plurality of fields to a user and receiving data from the user via at least a first subset of the plurality of fields, wherein the plurality of fields are arranged as on a clinical chart, wherein at least a second subset of the plurality of fields comprises a list of values, wherein the electronic record is to be reviewed by a health care reviewing organization, and wherein the selection user interface module adapted to facilitates the selection of at least a diagnosis;

at least one navigation module, wherein the at least one navigation module modifies the fields presented by the at least one user interface module in response to data entered into the user interface module; and

a verification module for determining an authorization level for the diagnosis by referring to at least data in identified fields, the verification module determining said authorization level prior to submission of the clinical record to a server computer.
2. (Currently Amended) The system of claim 1, wherein said user selection interface module further facilitates selection of one or more criteria corresponding to the a-selected diagnosis, and wherein the one or more criteria are selected by the navigation module from a set of criteria stored in a criteria database.
3. (Currently Amended) The system of claim 2 4, wherein said authorization level is determined at least in part by depends on a plurality of associated the selected criteria.
4. (Currently Amended) The system of claim 1, ~~further comprising a data entry interface,~~ wherein the ~~data entry~~ user interface module presents the plurality of fields in ~~is~~ a single

screen, ~~and interface~~ whereby ~~a~~ the user does need not scroll the screen when entering data in ~~at least the identified plurality of~~ fields.

5. (Previously Presented) The system of claim 1, wherein said verification module is coupled to a rule database which stores rules on the server computer and is employed by the verification module in determining said authorization level.

6. (Previously Presented) The system of claim 5, wherein the rule database stores at least two levels of rules, said levels comprising:

a criteria level, the criteria level rules determining a criteria status by referring to data from the identified fields of said clinical record; and

a diagnosis level, the diagnosis level rules determining a diagnosis authorization level by referring to the criteria status of associated criteria.

7. (Currently Amended) The system of in-claim 1, ~~when two or more computers are used,~~ wherein the user interface module is implemented on a client computer, further comprising:

~~—a user interface module on a client computer for generating screens to enable the submission of data to be submitted to the server computer;~~

~~—a user interface to facilitate the submission of clinical data to the server system, the user interface coupled with a forms database on the server computer that is used in generating user screens on the client system by which data is entered;~~

a first server computer database, housed on the server computer, wherein the first computer database is associated with the a user interface module, for storing wherein the first computer database stores forms and controls employed in the generation of the user interface, and wherein the user interface module causes the forms and controls to be presented in a format similar to a clinical chart ~~screens;~~

~~—a navigation module operatively coupled to the user interface module, the navigation module operable for user interaction with the user screens by automatically modifying fields of a respective user screen in response to a user's entering of data therein;~~

a second server computer database, housed on the server computer, wherein the second computer database is associated with the navigation module, and wherein the second computer database stores hierarchical for storing information representing as to data selections available to a user; and,

~~—a verification module operatively coupled to the user interface module, the verification module adapted to determine a level of authorization and criteria compliance based on the entered data, said determination performed prior to submission of the clinical record to the server; and~~

a third server computer database, housed on the server computer, wherein the third computer database is associated with the verification module, wherein the third computer database stores for storing criteria rules, and wherein the criteria rules which are evaluated on the client computer to determine in real-time whether each data entry meets one or more criteria for determining for an authorization level.

8. (Currently Amended) A method for facilitating the submission of a clinical record for automated processing, comprising:

providing at least one selection interface, wherein the selection interface adapted to facilitates the user selection by a user of one of a plurality of predetermined clinical data values, the predetermined clinical values comprising at least a record of the symptoms associated with a patient and a diagnosis;

receiving a selection from said selection interface; and

providing at least one data field in response to said selection, wherein the data field is a quantified data field associated with an objective criteria, and whereby said quantified data field is adapted to be examined so as to facilitates the automated processing of said clinical record.

9. (Currently Amended) A method for entering medical diagnosis-based ~~criteria~~ data, comprising:

entering a diagnosis into a database residing on a server computer;

entering a criteria into the database residing on the server computer, the criteria ~~corresponding to~~ associated with a rule required for ~~authorizing a~~ confirming the entered diagnosis, the criteria associated with at least one finding;

entering into the database residing on the server computer data corresponding to at least a subset of the at least one finding associated with the entered findings that meet criteria ~~into the database residing on the server computer~~; and

generating an electronic clinical record based on the entered data. ~~said finding~~.

10. (Currently Amended) The method of claim 9, further comprising a step of entering additional data corresponding to the at least one entered finding.

11. (Previously Presented) The method of claim 9, further comprising a step of entering a request for additional information by employing an additional request selection interface.

12. (Currently Amended) An interface for entering data for evaluation of a clinical encounter, comprising:

an interactive set of lists, wherein each of the lists in the interactive set of lists ~~each display in its own pop-up button list, and each list has its own domain;~~ wherein each of the lists in the interactive set of lists is displayed as a separate pop-up button list, and wherein the interactive set of lists is formatted to be similar to a clinical chart.

13. (Currently Amended) The interface of claim 12 further comprising a display area, wherein the a display area displays a parameter and at least one corresponding finding ~~findings~~ by displaying each parameter proximate to and the associated at least one finding ~~on a single line~~.

14. (Currently Amended) The interface of claim 12 further comprising a data entry area, wherein the a data entry area is adapted to facilitate entry of more than one finding for a parameter.

15. (Currently Amended) A method for processing patient clinical data by a health care organization, comprising:

establishing a server computer, wherein a plurality of forms facilitating the entry of patient clinical data in clinical chart form are stored on the server computer;

establishing a user site;

interconnecting the server computer and the user site;

retrieving from the server computer at least one of the plurality of forms for display and editing at the user site;

~~—, connected by an internet to a server computer providing forms at the user site that facilitate the entry of patient clinical data in clinical chart format;~~

configuring ~~inputs from~~ at least a first subset of the forms to apply a first set of rules to at least a first subset of inputs entered into the first subset of forms, wherein the first set of rules for authorizing authorizes at least one diagnosis based on associated clinical patient encounter criteria;

configuring ~~inputs from~~ at least a second subset of the forms to apply a second of set of rules to at least a second subset of inputs entered into the second subset of forms, wherein the second set of rules evaluates for clinical patient encounter data;

receiving patient clinical encounter data from ~~medical care providers~~ at least one user interacting with the user site; and

processing the received patient clinical encounter data automatically in accordance with the first and second set of rules.

16. (Cancelled)

17. (Currently Amended) The method of claim 15, further comprising providing an indication to a user of the user site regarding an authorization level for the entered data, wherein the indication is provided before the user submits the form to the user site.

18. (Currently Amended) A method for facilitating the single screen submission of patient clinical data in a computer implemented patient care review system, comprising:

providing ~~an~~ a clinical element selection interface, the clinical element selection interface facilitating the selection of ~~an~~ a clinical element, wherein the selectable clinical elements comprise at least one of history and exam;

providing a system/group selection interface, the system/group selection interface facilitating the selection of a ~~system-group~~ system/group associated with ~~of~~ the selected clinical element; and

providing a parameter selection interface, the parameter selection interface facilitating the selection of a parameter associated with ~~of~~ the selected system/group;
wherein the element selection interface, the system/group selection interface, and the parameter selection interface are displayed within a single screen.

19. (Currently Amended) A method for providing an indication of appropriateness of a patient clinical encounter to a user of ~~in~~ an electronic clinical charting system that facilitates the submission of diagnosis-relevant clinical data associated with the patient clinical encounter, comprising:

providing a criteria selection interface, wherein the criteria selection interface allows the user to select a diagnosis-based criteria;

receiving diagnosis related data from the user;

applying a verification rule to the received data; and

providing ~~an indication of~~ a verification result indication, the indication provided within each selected criterion in the criteria selection interface, and wherein the indication conveys ~~to indicate~~ each criterion authorization level.

20. (Currently Amended) The method of claim 19, wherein ~~review and download of patient clinical encounter encounters are done~~ information is presented on a user computer with relevant clinical data in clinical format that is familiar to clinicians and healthcare reviewers.

21. (Previously Presented) The method of claim 20, wherein criteria guided two-step clinical entry is done by users who are at least one of clinicians or clinician aids at the site of the patient encounter.

22. (Currently Amended) The method of claim 21 wherein two-step clinical entry of relevant clinical data ~~and is made in a uniform~~, screen display requiring no scrolling, and wherein the screen display which expedites the transformation of physical patient charts into electronic format for review by health care review organizations.

23. (Currently Amended) The interface of claim 12, wherein at least four pop-up button lists are displayed and include at least one of an Element pop-up button list, a System/Group pop-up button list, a Parameter pop-up button list, and a Finding pop-up button list.

24. (Previously Presented) The interface of claim 23, wherein a selection in one pop-up list populates ~~a list in~~ the next pop-up button list.
25. (Currently Amended) The interface of claim ~~23~~ 24, wherein
a selection in an Element pop-up button list populates a System/Group pop-up button list,
a selection in the System/Group pop-up button list populates a Parameter pop-up button list,
and
a selection in a Finding pop-up button list either:
a) enters the selected Finding with the selected Parameter into a chart note data field in the clinically formatted on-screen display; or
b) ~~directs prompts~~ a user to enter a numeric value, which when entered, enters the selected to be associated with the Finding, and wherein the Finding and with its associated value, along with the selected Parameter, are entered into a chart note data field in the clinically formatted on screen display.
26. (Currently Amended) The interface of claim 25, wherein a selection in a criteria ~~pop-up pop-up~~ button list ~~sets~~ populates the Element pop-up button list, System/Group pop-up button list, Parameter pop-up button list and Finding pop-up button list to enable the user to select the Finding.
27. (Previously Presented) The interface of claim 26, wherein only two steps are necessary to enter diagnosis-relevant clinical date:
a) a selection in the criteria pop-up list which either prompts selection of a finding from the Finding List, or
b) for a numerical finding, selects the finding and prompts for the numerical value.
28. (Previously Presented) The interface of claim 27, where similarly a selection in the additional info pop up list sets the Element list, System/Group list, Parameter list and Finding list to enable the user to select the Finding.
29. (Currently Amended) An electronic clinical record review system comprising:
a user interface, wherein the user interface that prompts for clinically relevant inputs which
are used to generate an electronic record of a patient clinical encounter;

a communications interface, whereby the electronic clinical record is transmitted to a health care reviewing organization for review; and ~~in real time for review by a health care reviewing organization and~~

a clinical data evaluation module, wherein the clinical data evaluation module that
automatically evaluates clinical data stored in the electronic clinical record for individual criteria and for the patient clinical encounter, the clinical data comprising patient symptoms.

REMARKS/ARGUMENTS

Claims 1-15, and 17-29 are currently pending in the instant application. Claims 1-4, 7-20, 22, 23, 25, 26, and 29 are amended herein. Applicant acknowledges receipt of the above-identified Office Action, and respectfully traverses the Office Action in its entirety.

RESPONSE TO EXAMINER'S CHARACTERIZATION OF PROVOST

Applicant thanks the Examiner for considering the arguments previously filed, but respectfully disagrees with the Examiner's characterization of both Provost et al., U.S. Patent No. 6,341,265 ("Provost") and Applicant's invention. In the Response to Arguments section beginning on page 16 of the Office Action, the Examiner argues that "clinical record" is broad and could be met by the "claim payment format" of Provost. Applicant respectfully disagrees. As claimed in the instant application, Applicant's invention is directed to the creation of electronic records of a patient clinical encounter. That is, the invention streamlines the process by which electronic records of patient clinical encounters can be created. Such electronic records may be created during a patient clinical encounter (e.g., by an attending physician or an assistant using a laptop, portable digital assistant ("PDA"), smart phone, or other portable computing device), or the electronic records may be created after the patient clinical encounter (e.g., by a physician, nurse, or other person transcribing the information from a paper form). By contrast, Provost's claim forms are used "to determine whether the patient is a beneficiary of an approved insurance plan" and "to determine whether the claim corresponds to health care services that are approved for payment" (Abstract). Provost's claim form is clearly meant to convey only the information necessary to authorize payment of the provider for the services rendered, and not to serve as a record of the patient clinical encounter.

The Examiner also argues that Provost teaches the approval of payment, but that the approval is based on the determination whether or not the diagnosis code and treatment codes are corresponding to the accepted procedures/services. As such, the Examiner argues, Provost teaches a form of authorizing diagnosis for the approving of payment. Applicant respectfully disagrees. Provost merely verifies that the insured, for whom a given claim form is being submitted, has insurance coverage for the services submitted by the provider. By way of example, some physicians dispense allergy shots, but not all insurance companies will pay for their insured to receive such shots. Provost's system uses "the claim form...to determine

whether the patient is a beneficiary of an approved insurance plan”, and to “determine whether the claim corresponds to health care services that are approved for payment”. Provost clearly does not authorize a diagnosis.

REJECTIONS UNDER 35 U.S.C. §112 SECOND PARAGRAPH

The Examiner rejected Claims 1-7, 9-14, and 18-29 under 35 U.S.C. §112, second paragraph. Applicant’s amendments having rendered the Examiner’s rejection moot, Applicant respectfully requests that the Examiner withdraw the rejection.

REJECTIONS UNDER 35 U.S.C. §101

The Examiner rejected Claims 1-8, 12-14, 18, and 23-28 under 35 U.S.C. §101. Applicant’s amendments having rendered the Examiner’s rejection moot, Applicant respectfully requests that the Examiner withdraw the rejection.

REJECTIONS UNDER 35 U.S.C. §102 - ANTICIPATION

The Examiner rejected Claims 8, 15, and 29 under 35 U.S.C. §102(b) as being anticipated by Provost. Applicant asserts that Provost is not proper prior art under 35 U.S.C. §102(b). For a reference to be proper prior art under 35 U.S.C. §102(b), the reference must have been publicly available “...more than one year prior to the date of the application for patent...”. The instant application claims the benefit of Provisional U.S. Patent Application Serial No. 60/247,246, filed November 7, 2000. As such, for a reference to be prior art against the instant application under 35 U.S.C. §102(b), the reference must have been publicly available prior to November 7, 1999. Provost was not publicly available until at least January 22, 2002. Therefore, Provost is not proper prior art under 35 U.S.C. §102(b).

For the purposes of this response, it is assumed that the Examiner intended to reject Claims 8, 15, and 29 under 35 U.S.C. §102(e) as being anticipated by Provost. The Court of Appeals for the Federal Circuit has consistently held that “Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim.” Lindemann Maschinenfabrik Gmbh v. American Hoist & Derrick, 221 USPQ 481, 485 (Fed. Cir. 1984). Applicant respectfully traverses the Examiner’s rejection as Provost does not contain disclosure of each and every element of Applicant’s claimed invention.

With respect to Claim 8, the Examiner argues that Provost discloses providing a selection interface, adapted to facilitate the user selection of one of a plurality of data values. Applicant respectfully traverses. Provost discloses a form comprising fields 44 “designed to receive and

display diagnosis codes representing the health care provider's diagnosis of the patient or the nature of the patient illness or injury" (Column 9, lines 36-39). Provost does not teach or suggest a selection interface adapted to facilitate the selection of one of a plurality of data values. Thus, Provost clearly does not anticipate Applicant's claimed invention as recited in Claim 8. In addition, Applicant's amendments have rendered the Examiner's remaining arguments moot, and Applicant respectfully requests that the rejection be withdrawn.

With respect to Claim 15, the Examiner argues that Provost discloses the clinical chart format recited in Applicant's claim. Applicant respectfully traverses. A clinical chart is a term of art in the medical community, and is well understood as a record of information relevant to the patient's health, including various aspects such as lab tests ordered and the results thereof, patient symptoms, and the like which are used to arrive at a diagnosis. By contrast, the form disclosed in Provost is designed to obtain payment for the treatments rendered, and therefore only includes information pertinent to billing and the determination of whether the charges are appropriate given the patient's health insurance, such as the ultimate diagnosis, the procedure(s) or service(s) performed, supplies used, etc. Provost clearly does not teach or suggest the clinical chart format recited in Applicant's claim, and Applicant respectfully requests that the Examiner withdraw the rejection of Claim 15 for at least this reason.

Applicant's amendments having rendered the Examiner's remaining arguments moot with respect to Claim 15, Applicant respectfully requests that the rejection be withdrawn.

With respect to Claim 29, the Examiner argues that Provost discloses a system which prompts for clinically relevant inputs used to generate an electronic record of a patient clinical encounter. Applicant respectfully traverses. As described above, Provost discloses a form for requesting payment for services rendered by a medical caregiver. Provost does not teach or suggest Applicant's claimed user interface which prompts for clinically relevant inputs used to generate an electronic record of a patient clinical encounter. Therefore, Applicant respectfully requests that the Examiner withdraw the rejection.

Applicant's amendments having rendered the Examiner's remaining arguments moot with respect to Claim 29, Applicant respectfully requests that the rejection be withdrawn.

Claims 18 and 19 are rejected under 35 U.S.C. §102(e) as being anticipated by Jacobs, U.S. Patent No. 6,049,794 ("Jacobs"). Applicant respectfully traverses the rejection in its entirety. However, in an effort to clarify the nature of Applicant's invention, Applicant has

amended Claims 18 and 19. Applicant's amendments having rendered the Examiner's rejection moot, Applicant respectfully requests that the Examiner withdraw the rejection.

Claims 12-14 and 23-28 are rejected under 35 U.S.C. §102(e) as being anticipated by Roberge et al., U.S. Patent No. 6,381,611 ("Roberge"). Applicant respectfully traverses the rejections in their entirety. However, in an effort to clarify the nature of Applicant's invention, Applicant has amended Claim 12. Applicant's amendments having rendered the Examiner's rejection moot, Applicant respectfully requests that the Examiner withdraw the rejection.

REJECTIONS UNDER 35 U.S.C. §103 - OBVIOUSNESS

The Examiner rejected Claims 9-11 and 17 under 35 U.S.C. §103(a) as being unpatentable over Provost. Applicant respectfully traverses the rejections in their entirety. However, in an effort to better clarify Applicant's invention, Applicant has amended Claims 9-10 and 17. Applicant's amendments having rendered the Examiner's rejection moot, Applicant respectfully requests that the Examiner withdraw the rejection.

The Examiner rejected Claims 20 and 21 under 35 U.S.C. §103(a) as being unpatentable over Jacobs. Applicant respectfully traverses the rejection. Claims 20 and 21 depend from Claim 19, and are patentable for at least the reasons set forth above with respect to Claim 19.

The Examiner rejected Claims 1-6 under 35 U.S.C. §103(a) as being unpatentable over Provost in view of Jacobs. Applicant respectfully traverses the rejection. It is well established that, to show obviousness, all limitations must be taught or suggested by the prior art. In Re Boyka, 180 U.S.P.Q. 580, 490 F.2d 981 (CCPA 1974); MPEP § 2143.03. It is error to ignore specific limitations distinguishing over the references. In Re Boe, 184 U.S.P.Q. 38, 505 F.2d 1297 (CCPA 1974); In Re Saether, 181 U.S.P.Q. 36, 492 F.2d 849 (CCPA 1974); In Re Glass, 176 U.S.P.Q. 489, 472 F.2d 1388 (CCPA 1973). Neither Provost nor Jacobs, nor the combination thereof, teaches or suggests a user interface module comprising a plurality of fields, wherein the plurality of fields are arranged as on a clinical chart, as recited in Applicant's Claim 1. Applicant respectfully asserts that Claim 1 is therefore distinguishable over the prior art, and withdrawal of the rejection thereto is respectfully requested. Claims 2-6 depend from Claim 1, and are patentable for at least the reasons set forth above with respect to Claim 1. Applicant therefore respectfully requests that the Examiner withdraw the rejection.

The Examiner rejected Claim 7 under 35 U.S.C. §103(a) as being unpatentable over Provost in view of Jacobs, and further in view of Roberge. Applicant respectfully traverses the

RESPONSE

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rejection. Neither Provost nor Jacobs nor Roberge, nor the combination thereof, teaches or suggests a user interface that causes forms and controls to be presented in a format similar to a clinical chart, as recited in Applicant's Claim 7. Applicant respectfully asserts that Claim 7 is therefore distinguishable over the prior art, and withdrawal of the rejection thereto is respectfully requested.

CONCLUSION

Having responded to all objections and rejections set forth in the outstanding Office Action, it is submitted that the currently pending claims are in condition for allowance and Notice to that effect is respectfully solicited. Additional characteristics or arguments may exist that distinguish the claims over the prior art cited by the Examiner, and Applicant respectfully preserves the right to present these in the future, should they be necessary. In the event that the Examiner is of the opinion that a brief telephone or personal interview will facilitate allowance of one or more of the above claims, he is courteously requested to contact applicant's undersigned representative.

Respectfully submitted,

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